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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,687	05/09/2002	Finbarr Paul Mary O'Harte	8830-8	5098
22832	7590	01/08/2004	EXAMINER	
KIRKPATRICK & LOCKHART LLP			RUSSEL, JEFFREY E	
75 STATE STREET			ART UNIT	PAPER NUMBER
BOSTON, MA 02109-1808			1654	

DATE MAILED: 01/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,687

Applicant(s)

O'HARTE ET AL.

Examiner

Jeffrey E. Russel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 8-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3, 10 and 14-19 is/are allowed.
- 6) ☒ Claim(s) 1, 4, 8, 11 and 13 is/are rejected.
- 7) ☒ Claim(s) 2, 5, 6, 9 and 12 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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1. Claims 4, 11, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. At claim 4, line 4, "and/or" (second occurrence) should be changed to "and" so that standard Markush terminology is used. At claim 11, line 3, "and/or" should be changed to "and" so that standard Markush terminology is used. At claim 13, line 3, the phrase "in addition to Tyr<sup>1</sup> glucitol GIP (1-42)" is unclear. At lines 2-3 of claim 13, the claim begins to recite amino acid substitutions or modifications at positions 1-3 of the GIP analogue. However, "Tyr<sup>1</sup> glucitol GIP (1-42)" is not a substitution or modification at positions 1-3 but rather, in and of itself, is an entire GIP analogue. It is not clear if "GIP (1-42)" should be deleted from the phrase in question. Alternatively, it may be that Applicants are claiming a composition comprising the peptide analogue comprising at least the 15 N-terminal amino acids of GIP(1-42) with at least one substitution or modification at position 1-3, combined with Tyr<sup>1</sup> glucitol GIP (1-42). Clarification is required.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1, 8, and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by the Fujii et al article (Chem. Pharm. Bull., Vol. 34, pages 2397-2410). The Fujii et al article teaches the chemical synthesis of human GIP. Prior to final deprotection of the 42-residue peptide, the tyrosine residue at position 1 is protected, i.e. modified, at N<sup>α</sup> with Z(OMe) and the glutamic acid residue at position 3 is protected, i.e. modified, at its sidechain with OChp. The protected 42-residue peptide is isolated as a powder. See Figure 2 and page 2407, fourth and fifth

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paragraphs. With respect to instant claim 8, an intended use limitation does not impart patentability to product claims which are otherwise anticipated by or obvious over the prior art.

4. Applicant's arguments filed November 13, 2003 have been fully considered but they are not persuasive.

Applicants argue that the Fujii et al article applied above does not teach analogs comprising a Tyr<sup>1</sup> glucitol residue. The examiner agrees. However, independent claim 1 does not require a Tyr<sup>1</sup> glucitol residue to be present - note the phrase "not including" at claim 1, line 3. Further, new claim 13, is unclear as to whether a Tyr<sup>1</sup> glucitol GIP residue must be present in the analogue. See the above rejection under 35 U.S.C. 112, second paragraph.

5. Claims 3, 10, and 14-19 are allowed. Claims 2, 5, 6, 9, and 12 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claim 4 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims. Claim 11 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

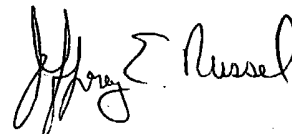
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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (703) 308-3975. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

PLEASE NOTE: Sometime on or around January 6, 2004, the examiner will be moving to the new USPTO headquarters. At that time, the examiner's phone number will change to (571) 272-0969. After January 6, it is recommended that Applicants attempt to contact the examiner at the new phone number if they are unable to reach him using the old number.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (703) 306-3220. The fax number for Technology Center 1600 for formal communications is (703) 872-9306; for informal communications such as proposed amendments, the fax number (703) 746-5175 can be used. The telephone number for the Technology Center 1600 receptionist is (703) 308-0196.



Jeffrey E. Russel  
Primary Patent Examiner  
Art Unit 1654

JRussel  
January 5, 2004